

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

ROSALYN WATER DISTRICT, NEW YORK,

Plaintiff,

vs.

MCKESSON CORPORATION; CARDINAL
HEALTH, INC.; AMERISOURCEBERGEN
CORPORATION; TEVA PHARMACEUTICAL
INDUSTRIES, LTD.; TEVA PHARMACEUTICALS Civil Action No. _____
USA, INC.; CEPHALON, INC.; JOHNSON &
JOHNSON; JANSSEN PHARMACEUTICALS,
INC.; ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; NORAMCO, INC.
ENDO HEALTH SOLUTIONS INC.; ENDO
PHARMACEUTICALS, INC.; ALLERGAN PLC
f/k/a ACTAVIS PLC; ALLERGAN FINANCE, LLC;
WATSON PHARMACEUTICALS, INC. n/k/a
ACTAVIS, INC.; WATSON LABORATORIES,
INC.; ACTAVIS LLC;
ACTAVIS PHARMA, INC. f/k/a WATSON
PHARMA, INC.; MALLINCKRODT, PLC d/b/a
MALLINCKRODT PHARMACEUTICALS;
MALLINCKRODT, LLC; CVS HEALTH
CORPORATION; RITE-AID OF MARYLAND, INC.
RITE AID CORP; WALGREENS BOOTS
ALLIANCE, INC.; WAL-MART INC.; JOHN DOES
1-100;

OPIATE LITIGATION
MDL NO. 2804

Defendants.

FIRST AMENDED COMPLAINT
(JURY TRIAL DEMANDED)

Plaintiff, ROSALYN WATER DISTRICT, NEW YORK (“Plaintiff”), brings this
Complaint against Defendants Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals
USA, Inc.; Cephalon , Inc.; Johnson & Johnson; Janssen Pharmaceuticals , Inc.; Ortho-

McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutical Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt plc; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; AmerisourceBergen Drug Corporation; CVS Health Corporation; Rite-Aid of Maryland, Inc., Rite Aid Corp; Walgreens Boots Alliance, Inc.; Wal-Mart Inc.; and John Does 1-100 (collectively “Defendants”) and alleges as follows:

I. PARTIES

A. PLAINTIFF, ROSALYN WATER DISTRICT, NY

1. Plaintiff is a special district organized and operating under New York State Town Law. *See* NY. CONST. ART. IX, § (h)(1); NY STAT LOC GOVTS § 10.

2. Plaintiff sustained economic damage as a result of Defendants’ wrongful conduct alleged herein, including: (a) costs for providing medical care to patients suffering from opioid-related addiction and injury; (b) costs for providing treatment, counseling, and rehabilitation services; (c) costs for providing treatment of infants born with opioid-related medical conditions; (d) increased costs of law enforcement and public safety relating to the opioid epidemic; (e) and costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered directly, by Plaintiff.

3. Plaintiff is authorized by law to abate any nuisance and prosecute in any court of competent jurisdiction any person who creates, continues, contributes to, or suffers such nuisance to exist and prevent injury and annoyance from such nuisance.

4. Plaintiff has standing to recover damages incurred as a result of Defendants' actions and omissions. Plaintiff has standing to bring all claims pled herein.

B. DEFENDANTS

5. The Manufacturer Defendants manufactured, marketed, and warned regarding the benefits and risks associated with the use of the opioid drugs. The Manufacturer Defendants failed their legal duty to prevent diversion by monitoring and reporting suspicious orders.

6. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVAPHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation which is registered to do business in New York and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

7. Cephalon, Inc. manufactures, promotes, and sells opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain." Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."

8. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for

Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

9. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder.

10. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock, and corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals’ drugs and Janssen’s profits inure to J&J’s benefit. NORAMCO, INC. (“Noramco”) is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC, is a Pennsylvania corporation registered to do business in New York with its principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceuticals,

Inc., Noramco, and J&J are referred to as “Janssen.”

11. Janssen manufactures, promotes, and sells drugs in the United States, including the opioid Duragesic (fentanyl). Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER.

12. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation registered to do business in New York with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as “Endo.”

13. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydome, in the United States. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

14. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS

PHARMA, INC. (f/k/a Actavis, Inc.) is registered to do business with the New York Secretary of State as a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis."

15. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

16. MALLINCKRODT, PLC is an Irish public limited company headquartered in Stainesupon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware and licensed to do business in New York. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc. Mallinckrodt, plc and Mallinckrodt, LC are referred to as "Mallinckrodt."

17. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of

Justice that it failed to detect and notify the Drug Enforcement Agency (“DEA”) of suspicious orders of controlled substances.

18. The Distributor Defendants placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Distributors universally failed to comply with federal and state law.

19. McKESSON CORPORATION (“McKesson”) operates as a licensed pharmacy wholesaler in New York. McKesson has its principal place of business in San Francisco, California.

20. CARDINAL HEALTH, INC. (“Cardinal”) operates as a licensed pharmacy wholesaler in New York. Cardinal Health, Inc. is an Indiana corporation with its principal place of business in Dublin, Ohio.

21. AMERISOURCEBERGEN DRUG CORPORATION (“AmerisourceBergen”) operates as a licensed pharmacy wholesaler in New York. AmerisourceBergen is a Delaware corporation which may be served through its registered agent for service of process. AmerisourceBergen’s principal place of business is in Chesterbrook, Pennsylvania.

22. CVS HEALTH CORPORATION (“CVS”) is a Delaware corporation with its principal place of business in Rhode Island. CVS, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States.

23. RITE-AID OF MARYLAND, INC. d/b/a RITE AID MID ATLANTIC CUSTOMER SUPPORT CENTER, INC. and RITE AID CORP (“Rite Aid”), are a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. Rite Aid, through its

various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Rite Aid, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids throughout the United States.

24. WALGREEN BOOTS ALLIANCE, INC., also known as Walgreen Co. (“Walgreens”) is a Delaware corporation with its principal place of business in Illinois. Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States.

25. WAL-MART, INC., formerly known as Wal-Mart Stores, Inc. (“Wal-Mart”), is a Delaware corporation with its principal place of business in Bentonville, Arkansas. Wal-Mart, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States.

26. Plaintiffs presently lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive. Plaintiffs will amend this Complaint to show their true names and capacities if and when they are ascertained. Plaintiffs are informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

II. JURISDICTION & VENUE

27. Plaintiff is diverse from all Defendants, therefore, this Court has jurisdiction as the

amount in controversy exceeds \$75,000.00.

28. This Court has personal jurisdiction over Defendants because they conduct business in New York.

29. Venue is proper in this district pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S. C. §§ 1391(b).

III. FACTUAL ALLEGATIONS

30. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs.

31. The Manufacturer Defendants disseminated information to pervert medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups.

32. Opioids are the most prescribed class of drugs. Sales of opioids in the United States have exceeded \$8 billion in revenue annually since 2009.

33. The Manufacturer Defendants wrongfully and tortuously continued their conduct with knowledge that such conduct was harming Plaintiff.

34. The Manufacturer Defendants spread their false and deceptive statements by marketing their opioids directly to doctors and patients in the Rosalyn Water District.

35. The Manufacturer Defendants marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and industry-funded

organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”). Defendants’ conduct is intentionally deceptive.

36. The Manufacturer Defendants deceptively marketed opioids in the Rosalyn Water District by advertising that opioid use generally is safe. By funding and directing this false marketing, the Manufacturer Defendants controlled the deceptive opioid messages.

37. The Manufacturer Defendants controlled the distribution of false messages in scientific publications, Continuing Medical Education (“CME”) programs, and medical conferences and seminars.

38. The Manufacturer Defendants sought to avoid FDA scrutiny in their effort to expand the opioid industry by intentionally disseminating falsely stated claims.

39. The Manufacturer Defendants falsely and misleadingly stated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants are belied by the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels on opioids to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

40. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. These drugs are not shown to be safe or effective for chronic pain.

41. Cephalon still conducts a campaign to promote Actiq and Fentora for chronic

pain and other non-cancer conditions for which it was not approved.

- a. Cephalon sponsored a CME that concluded a “[c]linically, broad classification of pain syndromes as either cancer- or non-cancer- related has limited utility” and recommended Actiq and Fentora for patients with chronic pain; and
- b. Cephalon’s sales representatives set up speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

42. Cephalon’s deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

43. Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In fact, Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

44. The Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the Rosalyn Water District. For example, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs.

45. The Manufacturer Defendants targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants

targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them.

46. The Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful.

47. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make its statements deceptive, including, but not limited to, the following:

- a. facilitating the distribution of patient education materials that contained deceptive statements;
- b. advertising deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. advertising in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. advertising falsely and inaccurately that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- e. falsely and wrongfully concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction;

- f. creating publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. supporting pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. supporting pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- j. endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

1. facilitating literature written by pro-opioid KOLs that deceived concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction; and
- m. making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

48. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make its statements deceptive, including, but not limited to, the following:

- a. creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;
- d. promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that

opioids were not efficacious and concealing this information;

- e. sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- f. providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- i. targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that

opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

- j. endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain, including the concept of pseudoaddiction;
- l. creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- m. targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- n. making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-

person detailing.

49. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- e. providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. endorsing and assisting in the distribution of CMEs

containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- g. endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid onset opioids;
- h. directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- i. making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

50. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make its statements deceptive, including, but not limited to, the following:

- a. making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- b. creating and disseminating advertisements that contained

deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

- c. creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

51. The Manufacturer Defendants profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive.

52. The Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and

“educational” materials in emails, correspondence and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo’s involvement. Other Manufacturer Defendants, such as Janssen, ran similar websites that masked their own role.

53. The Manufacturer Defendants manipulated their promotional materials to show that their claims were accurate when they were false. The Manufacturer Defendants foisted upon the medical community false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Medical professionals relied upon the Defendants’ false information in making treatment decisions. The Manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that Plaintiff now asserts. Plaintiff did not know of the existence of the Manufacturer Defendants’ fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

54. The Distributor Defendants owe a duty under both federal law (21 U.S.C. § 823, 21 CFR 1301.74) and New York law (10 CRR-NY 80.22), to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff’s Community as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff’s Community.

55. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

56. The Distributor Defendants breached their duties under state and federal law. These breaches caused diversion of prescription opioids for nontherapeutic purposes in the

Rosalyn Water District.

57. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the Rosalyn Water District. This diversion and the epidemic harmed Plaintiff.

58. The opioid epidemic in the Rosalyn Water District is a public nuisance and remains unabated.

59. The Distributor Defendants intentionally continued their conduct creating the opioid nuisance and causing Plaintiff's damages.

60. Opioids are a controlled substance and are categorized as "dangerous drugs" under New York law. *See* NY Crim Pro L § 715.05; NY PBH § 3306. These "schedule II" drugs are controlled substances with a "high potential for abuse."21 U.S.C. §§812(b), 812(2)(A)-(C).

61. As wholesale drug distributors, each Distributor Defendant was required under New York law to obtain a license as a wholesaler of controlled substances. NY PBH Article 33. Each Distributor Defendant is licensed by the New York Department of Health and is a "registrant" or "licensee" as a wholesale distributor in the chain of distribution of Schedule II controlled substances and assumed a duty to comply with all security requirements imposed under the regulations adopted by the New York Department of Health.

62. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. §0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

63. Each Distributor Defendant has an affirmative duty under federal and New York law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. §§823(b)(I).

64. The New York Department of Health requires that drug wholesalers “shall establish and operate a system to disclose to the licensee suspicious orders for controlled substances and inform the department of such suspicious orders. Suspicious orders shall include, but not be limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” Rule 80.22.

65. Federal regulations, similarly, impose a non-delegable duty upon wholesale drug distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. §1301.74(b).

66. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.

67. The Distributor Defendants admit that they are responsible for reporting suspicious orders.

68. The Distributor Defendants admit that they have not only statutory and regulatory

responsibilities to detect and prevent diversion of controlled prescription drugs.

69. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in the Rosalyn Water District and/or to retailers from which Defendants knew prescription opioids were likely to be diverted in the Rosalyn Water District.

70. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

71. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

72. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

73. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State and Plaintiff's Community.

74. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nontherapeutic purposes.

75. Plaintiff is damaged by the harm resulting from the diversion of prescription opioids for nonmedical purposes.

76. The sheer volume of prescription opioids distributed to pharmacies in the Rosalyn Water District is excessive for the medical need of the community.

77. The Distributor Defendants failed to report "suspicious orders" originating from the Rosalyn Water District.

78. The Distributor Defendants unlawfully filled suspicious orders of unusual size,

orders deviating substantially from a normal pattern.

79. The Distributor Defendants breached their duty to monitor, refuse and report suspicious orders of prescription opiates originating from the Rosalyn Water District.

80. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

81. The Distributor Defendants breached their duty to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and failed to inform the authorities including the DEA of suspicious orders when discovered.

82. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders.

83. The federal and state laws at issue here are public safety laws.

84. The Distributor Defendants’ violations of public safety statutes constitute *prima facie* evidence of negligence under State law.

85. The Distributor Defendants’ conduct is purposeful and intentional.

86. The Distributor Defendants acted with a conscious disregard for the rights and safety of other persons. Said actions have a great probability of causing substantial harm.

87. The Distributor Defendants’ repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

88. Defendants agreed among themselves to set up, develop, and fund an unbranded

promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids, to increase sales, revenue, and profit from their opioid products.

89. This interconnected and interrelated network relied on the Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by Defendants intended to mislead consumers and medical providers of the appropriate uses, risks, and safety of opioids.

90. Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, the dissemination, and reinforcement of nine false propositions: (a) that addiction is rare among patients taking opioids for pain; (b) that addiction risk can be effectively managed; (c) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed "pseudoaddiction"; (d) that withdrawal is easily managed; (e) that increased dosing presents no significant risks; (f) that long-term use of opioids improves function; (g) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (h) that use of time-released dosing prevents addiction; and (i) that abuse-deterring formulations provide a solution to opioid abuse.

91. Defendants knew that none of these propositions is true and that there was no evidence to support them. Each Defendant worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, health care providers, and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

92. Defendants' unbranded promotion and marketing network was a successful marketing tool that achieved marketing goals that would have been impossible to have been met

by a single or even a handful of the network's distinct corporate members.

93. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the creation of Front Groups. These collaborative networking tactics allowed each Defendant to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Defendants.

94. Defendants worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, Defendants were able to create a false consensus through their materials and references.

95. An illustrative example of Defendants' utilization of this tactic is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

96. Nonetheless, Defendants widely and repeatedly cited this letter as proof of the low addiction risk in connection with taking opioids in connection with taking opioids despite its obvious shortcomings. Defendants' egregious misrepresentations based on this letter included claims that less than one percent of opioid users became addicted.

97. Defendants' collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers that opioids were not a concern.

98. Defendants took advantage of the industry structure, including end-running its internal checks and balances, to their collective advantage. Defendants agreed among themselves to increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from their opioid products.

99. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly knit industry.

100. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

101. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below, including, for example, membership in the Healthcare Distribution Alliance (“HDA”).

102. Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the NYCSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach—to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants’ agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other’s compliance with their reporting obligations.

103. Defendants were, both individually and collectively, aware of the suspicious orders that flowed directly from Defendants’ facilities.

104. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

105. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

106. The desired consistency and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

COUNT I
PUBLIC NUISANCE
(Against all Defendants)

107. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

108. Defendants engaged in conduct which endangers the health, safety or comfort of a considerable number of persons.

109. Defendants' actions damaged all members of the public.

110. Defendants' conduct and subsequent sale of their opioid products resulted in interference with the public health.

111. The public nuisance created by Defendants is within the control of Defendants.

112. The public nuisance created by Defendants is the result of repeated and continuing conduct which requires the expenditure of funds by Plaintiff on an ongoing and

continuous basis.

113. Defendants have tortuously caused and permitted dangerous drugs under their control to be diverted such as to injure Plaintiff's Community and its residents.

114. Defendants have wrongfully distributed opioids without maintaining effective controls against diversion.

115. Defendants caused interference with the public health, safety, and welfare to be free from reasonable apprehension of danger to person or property.

116. Defendants' conduct in illegally distributing and selling prescription opioids, or causing such opioids to be distributed and sold, where Defendants know, or reasonably should know, such opioids will be diverted and possessed and/or used illegally in Plaintiff's Community is of a continuing nature.

117. Defendants' actions have been of a continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

118. A violation of any rule or law controlling the distribution of a drug of abuse in Plaintiff's Community and the State is a public nuisance.

119. Defendants' distribution of opioids while failing to maintain effective controls against diversion was proscribed by statute and regulation.

120. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Plaintiff's Community will be diverted, leading to abuse, addiction, crime, and public health costs

121. Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare, and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and

property.

122. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety and welfare, and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

123. Defendants know, or reasonably should know, that their conduct causes an unreasonable invasion of the public right to health, safety and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

124. Defendants' conduct in wrongfully marketing, distributing, and selling prescription opioids creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to residents in Plaintiff's Community and otherwise interfere with public health.

125. Defendants' conduct caused death and injury to residents in the Rosalyn Water District and will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

126. Defendants' conduct caused their drugs to be widely available and used to the harm of Plaintiff.

127. Defendants' conduct is a direct and proximate cause of deaths and injuries to the residents of the Rosalyn Water District.

128. Defendants' conduct is a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the residents of Plaintiff's Community, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security all to its economic detriment.

129. Defendants' actions created and expanded the abuse of opioids, which

expenses tortuously injured Plaintiff economically.

130. Defendants knew the method by which they got opioids to the public increased to diversion and caused Plaintiff's economic hardship.

131. Defendants acted recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

132. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm

133. The damages available to Plaintiff include, *inter alia*, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance which the government seeks to abate. Defendants' conduct is ongoing and persistent, and Plaintiff seeks all damages flowing from Defendants' conduct.

134. Plaintiff seeks to abate the nuisance and harm created by Defendants' conduct.

135. As a direct result of Defendants' conduct, Plaintiff and Plaintiff's Community have suffered actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services. Plaintiff here seeks recovery for its own harm.

136. Plaintiff and Plaintiff's Community have sustained specific and special injuries because its damages include, *inter alia*, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

137. Plaintiff further is entitled to abate the nuisance created by the Defendants.

138. Defendants' conduct is a continuing nuisance.

139. The Rosalyn Water District has sustained, and continues to sustain injuries because its damages include, *inter alia*, health services and law enforcement expenditures.

140. Plaintiff seeks economic losses resulting from Defendants' fraudulent activity and fraudulent misrepresentations.

141. Plaintiff seeks all legal and equitable relief as allowed by law including, *inter alia*, abatement, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT II
NEGLIGENCE
(Against All Defendants)

142. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

143. Plaintiff seeks economic damages which were the foreseeable result of Defendants' intentional and/or unlawful actions and omissions.

144. Under State law, to establish actionable negligence, one must show in addition to the existence of a duty, a breach of that duty, and injury resulting proximately therefrom. All such essential elements exist here.

145. Each Defendant had an obligation to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs to the State and Plaintiff.

146. Each Defendant had an obligation to exercise due care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs in the State and Plaintiff's Community.

147. The existence of a duty depends on the foreseeability of the injury. Each Defendant owed a duty to Plaintiff and to Plaintiff's Community because the injuries alleged herein were foreseeable, and in fact foreseen, by Defendants.

148. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

149. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

150. Moreover, Defendants were repeatedly warned by law enforcement of the unlawfulness and consequences of their actions and omissions.

151. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

152. As described above in language expressly incorporated herein, the Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution

of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm-diversion of highly addictive drugs for non-medical purposes -the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

153. As described elsewhere in the Complaint in language expressly incorporated herein, the Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Plaintiff's Community and destinations from which they knew opioids were likely to be diverted into Plaintiff's Community, in addition to other misrepresentations alleged and incorporated herein.

154. As described elsewhere in the Complaint in language expressly incorporated herein, the Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, and by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drugs were not safe or suitable.

155. The Manufacturer Defendants misrepresented and concealed the addictive nature of prescription opioids and their lack of suitability for chronic pain, in addition to other misrepresentations alleged and incorporated herein.

156. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

157. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

158. The causal connection between Defendants' breaches of duties and misrepresentations and the ensuing harm was entirely foreseeable.

159. As described above in language expressly incorporated herein, Defendants' breaches of duty and misrepresentations caused, bears a causal connection with, and/or proximately resulted in the damages sought herein.

160. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels. However, Defendants breached their duties to monitor for, report, and halt suspicious orders, breached their duties to prevent diversion, and, further, misrepresented what their duties were and their compliance with their legal duties.

161. Defendants' unlawful and/or intentional actions create a rebuttable presumption of negligence under State law.

162. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' actions and omissions. Plaintiff does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

163. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, *inter alia*, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT III
NEGLIGENCE PER SE
(Violation of New York Controlled Substance Act and
the New York Department of Health Rules and Regulations)

164. The New York Controlled Substances Act (“NYCSA”), NYS Public Health Law Article 33, § 3300 *et seq.*, provides, in relevant part, that “No person shall manufacture or distribute a controlled substance in this state without first having obtained a license to do so from the department.” NYSCA § 3310(1). For purposes of the NYSCA, a “person” is defined as “individual, institution, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.” NYSCA § 3302(25).

165. Similarly, Rule 80.22 of the New York Department of Health Rules and Regulations provides, in part, that drug wholesalers “shall establish and operate a system to disclose to the licensee suspicious orders for controlled substances and inform the department of such suspicious orders. Suspicious orders shall include, but not be limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

166. The New York Department of Health Rules require manufacturers of controlled substances to “keep records of all controlled substances manufactured, received, disposed of or distributed by them, which shall include date of manufacture, type and quantity of drug manufactured.” Rule 80.23. And “Distributors, importers and exporters shall keep records of all controlled substances received, disposed of or distributed by them.” Rule 8.23(b).

167. Defendants, as distributors of controlled substances, are expected to comply both with the laws of the State into which they distribute controlled substances and with industry custom and standards. In the instant case, New York law and the standard of conduct for Defendants’ industry require that the Defendants know their customers, which includes *inter*

alia, an awareness of the customer base, knowledge of the average prescriptions filled each day, the percentage of controlled substances compared to overall purchases, a description of how the dispenser fulfills its responsibility to ensure that prescriptions filled are for legitimate medical purposes, and identification of physicians and bogus centers for the alleged treatment of pain that are the dispenser's most frequent prescribers.

168. Defendants have failed to diligently respond to the suspicious orders which Defendants have filled.

169. Defendants have failed to provide effective controls and procedures to guard against diversion of controlled substances in contravention of New York law.

170. Defendants have willfully turned a blind eye towards the actual facts by regularly distributing large quantities of controlled substances to retailers and dispenser who are serving a customer base comprised of individuals who are themselves abusing and/or dealing prescription medications, many of whom are addicted and all of whom can reasonably be expected to become addicted. Defendants negligently acted with others to violate New York's drug laws, dispensing controlled substances for illegitimate medical purposes, operating bogus pain clinics which do little more than provide prescriptions for controlled substances and thereby creating and continuing addictions to prescription medications in this state.

171. Defendants have, by their acts and omissions, proximately caused and substantially contributed to damages to the Rosalyn Water District by violating New York law, by creating conditions which contribute to the violations of New York laws by others, and by their negligent and/or reckless disregard of the customs, standards and practices within their own industry.

172. The Rosalyn Water District seeks to restrain the violations of New York law.

173. The Rosalyn Water District has, in the past, sustained enormous damages as the proximate result of the failure by Defendants to comply with the New York Controlled Substance Act and the Rules and Regulations of the New York Department of Health. Unless restrained by injunctive relief, the Rosalyn Water District will continue to suffer losses as the proximate result of the failure by Defendants to monitor and to disclose suspicious orders of controlled substances.

174. Plaintiff has suffered irreparable harm and will in the future continue to suffer irreparable harm unless Defendants are restrained by an injunction.

175. A lawsuit for damages for past losses as sustained by the Rosalyn Water District is an inadequate remedy to prevent future losses which will result from the failure by Defendants to comply with New York law.

COUNT IV
DECEPTIVE TRADE PRACTICES ACT N.Y. GBL § 349
(Against All Defendants)

176. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

177. New York General Business Law Section 349 (“GBL § 349”) declares unlawful “[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state . . .”

178. Each Defendant represented that opioids had certain characteristics, approvals, uses, and benefits that were false and failed to report and/or prevent the diversion of highly addictive prescription drugs to illegal sources.

179. The Defendants also omitted material facts, causing confusion or misunderstanding as to approval or certification of goods or services.

180. The Defendants failed to disclose the material facts that, *inter alia*, they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell opioids, and the Distributor Defendants would not have been able to receive and renew licenses to sell opioids.

181. Defendants' unfair, deceptive, and unconscionable representations, concealments, and omissions were reasonably calculated to deceive the State, the public, Plaintiff's Community, and Plaintiff.

182. Defendant's unfair, deceptive, and unconscionable representations, concealments, and omissions were consumer-oriented.

183. As described more specifically above, Defendants' representations, concealments, and omissions constitute a willful course of conduct which continues to this day.

184. Because of the dangerously addictive nature of these drugs, the Defendants' manufacturing, marketing, sales, and/or distribution practices unlawfully caused an opioid and heroin plague and epidemic in the State and Plaintiff's Community. Each Defendant had a non-delegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate medical, scientific, and industrial channels.

185. The conduct of Defendants alleged herein constitutes recurring, "unlawful" deceptive acts and practices in violation of GBL § 349, and as such, Plaintiff seeks monetary damages and the entry of injunctive relief against Defendants.

186. As alleged herein, each Manufacturer Defendant wrongfully represented that the

opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have.

187. The Manufacturer Defendants also wrongfully misrepresented that the opioids were safe and effective when such representations were untrue, false, and misleading.

188. The Manufacturer Defendants also used exaggeration and/or ambiguity as to material facts and omitted material facts, which tended to deceive and/or did in fact deceive.

189. The Manufacturer Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Manufacturer Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

190. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value, and in fact caused addiction and overdose deaths; therefore, Defendants' sales and marketing of opioids constituted a violation of State law.

191. Because of the dangerously addictive nature of these drugs, the Manufacturer Defendants' marketing, sales, and distribution practices unlawfully caused an opioid and heroin plague and epidemic in the State and Plaintiff's Community. Each Defendant had a non-delegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate medical, scientific, and industrial channels.

192. As alleged herein, each Distributor Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have.

193. The Distributor Defendants also wrongfully misrepresented that the opioids were safe and effective when such representations were untrue, false, and misleading.

194. The Distributor Defendants also used exaggeration and/or ambiguity as to material facts and omitted material facts, which tended to deceive and/or did in fact deceive.

195. The Distributor Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Distributor Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Manufacturer Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

196. Because of the dangerously addictive nature of these drugs, which the Distributor Defendants concealed and misrepresented, they lacked medical value, and in fact caused addiction and overdose deaths; therefore, Defendants' sales and marketing of opioids constituted a violation of State law.

197. Because of the dangerously addictive nature of these drugs, the Distributor Defendants' marketing, sales, and distribution practices unlawfully caused an opioid and heroin plague and epidemic in the State and Plaintiff's Community. Each Defendant had a non-delegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate medical, scientific, and industrial channels.

198. Plaintiff seeks an injunction preventing Defendants from continuing to make statements in violation of N.Y. GBL § 349.

199. Plaintiff seeks recovery of costs and attorneys' fees in accordance with N.Y. GBL § 349(h).

JURY DEMAND

Plaintiff demands a trial by jury on all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays that this Court grant the following relief:

- A. entering Judgment in favor of Plaintiff in a final order against each of the Defendants;
- B. enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with it, from engaging in unfair or deceptive practices in violation of law and ordering a temporary, preliminary or permanent injunction;
- C. ordering that Defendants abate the ongoing public nuisance caused by the opioid epidemic;
- D. ordering that Defendants compensate Plaintiff for the costs to abate the ongoing public nuisance caused by the opioid epidemic;
- E. ordering Defendants to fund an abatement fund for the purposes of abating the opioid nuisance;
- F. awarding actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorney fees and all costs and expenses of suit to the extent permitted by law;
- G. awarding Plaintiff the damages caused by the opioid epidemic, including (i) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (ii) costs for providing treatment, counseling, and rehabilitation services; (iii) costs for providing treatment of infants born with opioid-related medical conditions; (iv) costs for

providing care for children whose parents suffer from opioid related disability or incapacitation; and (v) costs associated with law enforcement and public safety relating to the opioid epidemic;

H. awarding judgment against the Defendants requiring Defendants to pay punitive damages; and

I. granting Plaintiff (i) the cost of investigation, reasonable attorneys' fees, and all costs and expenses; (ii) pre-judgment and post-judgment interest; and (iii) all other relief as provided by law and/or as the Court deems appropriate and just.

Dated, this the 15th day of November, 2019.

Attorneys for Plaintiffs
ROSALYN WATER DISTRICT, NY

/s/Mark A. Tate
Mark A. Tate
Georgia Bar No. 698820
TATE LAW GROUP, LLC
2 E. Bryan Street, Suite 600
Savannah, GA 31401
Telephone (912) 234-3030
Fax (912) 234-9700
marktate@tatelawgroup.com

David Grossman
New York Bar No. 2693919
Dennis Kelly
New York Bar No. 2205151
GROSSMAN & KELLY, LLP
1248 Montawk Highway
W. Islip, NY 11795
Telephone (631) 352-0146
Fax (631) 352-0147
dgrossman@kellyandgrossman.com
dkelly@kellyandgrossman.com

Riccardo Iaccarino
New York Bar No. 2314557
BARNES, IACCARINO & SHEPHERD, LLP

3 Surrey Lane
Hempstead, NY 11550
Telephone: (516) 483-2990
Fax (516) 483-0566
riaccarino@bislawfirm.com